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Predictive factors for the outcome of anterior cervical decompression and fusion

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Abstract In a prospective study, 103 patients were randomised to anterior cervical decompression and fusion (ACDF) with a cervical carbon-fibre intervertebral fusion cage or the Cloward procedure. Preoperative background variables, active range of neck motion, handgrip strength, radiological evaluation and subjective variables were used in a multiple regression model to find the strongest predictors of postoperative outcome as measured by current pain intensity and the Neck Disability Index (NDI). Male sex, greater kyphosis at the level operated on, non-smoking, a greater neck mobility in right rotation, low disability on NDI, and older age were predictors of pain reduction and explained 30% of current pain intensity at follow-up. Higher educational level, non-smoking, greater kyphosis at the level operated on, a greater flexion mobility, greater right handgrip strength and lower current pain intensity were predictors of improvement, and explained 28% of the postoperative outcome on NDI. The most important predictor for postoperative pain intensity was the magnitude of the preoperative kyphosis. Preoperative pain intensity was the most important predictor for improved NDI. At follow-up about 70% of the patients still had deficit based on current pain intensity and NDI, and 44% had remaining dysfunction based on Odom's criteria. In conclusion, the multivariate analysis shows that male sex, non-smoking, greater segmental kyphosis and a low pain and disability level are preoperative predictors of a good outcome in ACDF. In addition, the study suggests the importance of other predictive variables than those studied for the outcome of ACDF.

Keywords Cervical spine · Intervertebral fusion · Prognostic factors · Outcome

Introduction

Many authors have reported the results of anterior cervical decompression and fusion (ACDF) in cervical radiculopathy [6, 24, 29]. The best results have been reported for young male patients with soft disc disease [3, 9, 14] at a single level [3, 9], radicular pain without additional neck or lumbar pain [12, 14], correlation between radiological and clinical findings [14], and short duration of symptoms [3, 9, 14]. The preoperative predictive value of objective variables such as radiological findings, active range of motion (AROM) in the neck and handgrip strength has not been determined.

In previous studies of ACDF the outcomes have been determined by pain quantification or by Odom's criteria [21], and there are only limited reports on functional outcome [23, 29]. Except for Eriksen et al. [9], all previous reports have used only chi-square test or bivariate correlation analysis, with no potential to control for interdependency between variables. The present study used multivariate analysis with quantification of the relative importance of each variable studied. Determination of predictive factors may be of great importance, since a large

number of patients have remaining symptoms after ACDF. One year after ACDF with a cervical carbon-fibre intervertebral fusion cage (CIFC), 82% of patients reported ≥10 mm average pain on a visual analog scale (VAS) and ≥20% disability on the Neck Disability Index (NDI) [23].

The purpose of the present study was to investigate predictive factors for the outcome of ACDF with CIFC and with the Cloward procedure using autograft (CP) as measured by current pain intensity on VAS and disability measured with NDI. Another purpose was to investigate whether the patients have remaining deficit after ACDF.

Materials and methods

Patients, inclusion and exclusion criteria

After giving their informed consent, 103 patients were randomised to either the CIFC (AcroMed, Cleveland, Ohio), using a similar technique to the Smith-Robinson tricortical graft procedure [29], or the traditional CP with bicortical autograft harvested through a 5-cm skin incision using a Cloward dowel cutter [6, 29]. The inclusion criteria were at least 6 months' duration of neck pain and radiculopathy of degenerative origin, with compatible magnetic resonance imaging (MRI) and clinical findings. Exclusion criteria were myelopathy, diagnosed mental disease, drug abuse and previous spine surgery.

All patients asked to take part agreed. In the outpatient clinic, 52 patients were randomly assigned to the CIFC and 51 patients to the CP by the attending nurse who picked from a box one of two possible notes, reading either CP or CIFC. Thus, each patient had a 50% likelihood of being operated on by CIFC or the CP. The randomization resulted in a similar distribution of age, gender, number of levels operated on, duration of symptoms and smoking habits in the two groups.

Preoperatively and at annual follow-ups all patients underwent a standard clinical examination, radiographs (anteroposterior, lateral and oblique), and answered questionnaires. A junior doctor acted as an independent observer and assisted patients with filling out the questionnaires. There were 89 patients remaining at both the 1-year and the 2-year follow-ups. However, complete radiological and outcome data were obtained in 74 patients at the 1-year and 44 patients at the 2-year follow-up. The last result from the individual was used in the statistical analysis according to the intention-to-treat approach. Data from 74 patients (72%) were used in the analysis. Of these 74, 40 were in the CIFC group and 34 in the CP group, 37 men and 37 women, with a mean age of 48 (SD 8, range 31–67) years, and 45% were smokers. The mean follow-up time for complete data was 19 months (SD 6, range 12–24 months). The surgery was performed in a standardized fashion as previously described [29]. Forty-five of the 74 patients were operated at one segmental level (level= 1), 26 patients at two segmental levels (level= 2), and three patients at three (level= 3). The postoperative handling included a Philadelphia collar for 6 weeks, and most patients received general physiotherapy in primary care after removal of the collar.

The Ethics Committee at the Faculty of Health Sciences, Linköping University, approved the study.

Measurements

Background factors

Background data included: gender (1= man, 2= women), age, family situation (1= living with the family, 2= living alone), level of education (1= elementary school, 2= vocational school, 3= high school, 4= university), type of work (1= blue collar, 2= white collar), work status (1= no sick leave, 2= part-time sick-leave, 3= full-time sick leave), smoking habits (1= yes, 2= no), localisation of current problems (0= neck, 1= arm/neck and arm), duration of current episode in months (1= at least 6 months but not as much as 12 months, 2= 12 months but not as much as 36 months, 3= 36 months or more), and use of analgesics (1= yes, 2= no).

Objective variables

The cervical measurement system (CMS) equipment (David Back Clinic International, Vantaa, Finland) was used to measure the active range of motion (AROM) in the neck in the six conventional movement directions of the cervical spine (flexion, extension, lateral flexion to the right and to the left, rotation to the right and to the left). The CMS helmet consists of a plastic frame with two gravity goniometers, a compass, and two spirit levels attached to the frame. The dial meters are marked in two-degree increments. The CMS had earlier been shown to be a reliable and valid method [22]. The placement of the CMS, the test position and the test procedure were standardized [22].

Strengths of the right and left handgrip were measured in kiloPascals (kPa) with a Vigorimeter (Gebrüder Martin, Tuttlingen, Germany). The Vigorimeter consists of a rubber bulb connected to a manometer and has been shown to be reliable in a previous study [17]. A large size of bulb was used in this test.

Radiographs (AP, lateral and oblique) were obtained preoperatively and postoperatively at annual follow-ups. A radiologist and a spine surgeon independently assessed fusion status with no knowledge of the clinical outcome. In case of a differing opinion between the two observers, a combined assessment was made and agreement was reached on the classification. The fusion was classified into four types according to the presence or not of bridging bone anterior to and/ or through the disc space. A type 1A fusion was defined as bridging bone anterior to and through the disc space; IB as bridging bone anterior to but not through the disc space; 2A as bridging bone through but not anterior to the disc space; and 2B as no bridging bone at all. The treatment was classified as having resulted in a pseudarthrosis (=2) if a 2B healing was observed at any level, and if not, as fused (=1).

Segmental height was measured in millimeters with a ruler at the most anterior aspect of the disc. Variations in the magnification were controlled for by relating the disc height to the anterior–posterior length of C2 or C7.

Segmental lordosis/kyphosis was measured with a protractor at the motion segment operated on, and defined as the angle between the cranial and caudal endplates of the upper and lower vertebrae respectively. If several adjacent segments were treated, the segmental lordosis/kyphosis was defined as the angle between the endplates cranial and caudal to the levels operated on [29].

Subjective variables

Pain was quantified by a horizontal 100-mm VAS (0=no pain, 100=worst imaginable pain), for "pain right now" (current pain intensity) and "worst pain last week" [25].

Pain drawings of the front and the back of the body were coded by a senior orthopedic surgeon as organic (=1), possibly organic (=2), possibly non-organic (=3), and non-organic (=4) [28].

Neck-specific disability was quantified by the NDI. The ten sections of the NDI (pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation) are scored from 0 to 5, added together and transformed into percentages (0% = no pain or difficulties, 100% = highest score for pain and difficulty on all items) [30].

An independent doctor evaluated the outcome of the surgery regarding the criteria drawn up by Odom [21] (excellent=1, good=2, fair=3, poor=4).

Statistical methods

Correlations between the background/preoperative factors and postoperative current pain and NDI, at the last follow-up, were determined by Spearman rank correlation coefficient analysis. Independent variables such as initial background factors, objective variables, subjective variables, and surgical procedure factors that correlated ($P \leq 0.1$) with the postoperative outcome (current pain intensity and NDI) were used in a standard linear multiple regression analysis, and this was followed by a statistical forward stepwise regression procedure to reveal the most important factors. For the regression model, adjusted R^2, β, b-value, and standard error b were used. The adjusted R^2 is the proportion of variation in the dependent variable that is explained by the independent variables, adjusted for number of variables assigned in the analysis. The β value is the standardized regression coefficient, which explains which independent variables are most important in predicting the dependent variable. It is calculated as if all of the independent variables had means of 0 and variance of 1. Because, except for a greater proportion of women in the CIFC group ($P=0.04$), there were no significant differences between patients operated on by the CP and the CIFC methods, either before or after the surgical procedure [29], the CP and the CIFC groups were analyzed together. P-values of ≤ 0.05 were considered to be statistically significant.

For deficit, the following cut-off points were used: for current pain intensity on VAS ≥ 10 mm [7], for NDI ratings $\geq 20\%$ [11], and a fair or poor outcome by Odom's criteria. The last results of measurements of the dependent variables from each individual was used in the statistical analysis according to the intention-to-treat approach. The reason for this is that, in several patients, various data points were missing. However, there were no differences, either initially or at the 1-year follow-up, between those who completed the study and those who did not, and there was no indication that any data points were systematically missing for specific patient categories. Descriptive statistics of the patient material has been previously described by Vavruch et al. [29].

Results

Collinearity

In general there was no collinearity (intercorrelation) ($r<0.8$) [27] between the independent variables (Table 1).

Current pain intensity

Bivariate analysis

Ten preoperative variables: male gender, older age, greater segmental kyphosis, non-smoking, greater neck AROM in right rotation, greater right and left handgrip strength, organic type of pain drawing, low disability on NDI, and low current pain intensity on VAS were significantly ($P \leq 0.1$) correlated with low current pain at the last follow-up (Table 2).

Right and left handgrip strength and pain drawing were excluded from the multiple regression models because they lowered the adjusted R^2 value. Also, the initial current pain variable was excluded in the multiple regression models in order to reduce the number of independent variables.

Table 1 The Spearman rank correlation coefficient (intercorrelation) between the preoperative variables that were found to have a correlation (P-value ≤ 0.1) with current pain intensity and/or the Neck Disability Index (NDI) at follow-up (R right, L left)

	Gender	Age	Education	Smoking	Kyphosis	Flexion	Lat. flex. R	Rot. R	Hand-grip R	Hand-grip L	Current pain	Pain drawing	NDI
Gender	1.00	0.14	0.20	0.21	0.03	0.11	0.06	-0.08	-0.45	-0.34	0.32	0.58	0.25
Age			-0.02	0.19	-0.02	-0.08	-0.23	-0.15	-0.08	-0.12	-0.03	0.17	0.02
Education				0.31	0.17	0.19	0.18	0.19	0.09	0.24	0.12	0.21	-0.02
Smoking					0.28	0.23	0.18	0.23	0.28	0.14	0.03	0.22	0.03
Kyphosis						0.34	0.15	0.15	-0.13	-0.11	-0.04	-0.09	-0.07
Flexion							0.53	0.52	0.24	0.12	-0.26	0.11	-0.30
Lat. flex. R								0.65	0.32	0.26	0.0004	0.14	-0.14
Rot. R									0.41	0.17	-0.16	-0.02	-0.21
Handgrip R										0.58	-0.23	-0.14	-0.18
Handgrip L											-0.01	-0.04	-0.06
Current pain												0.25	0.51
Pain drawing													0.30
NDI													1.00

Table 2 Spearman rank correlation coefficient analysis ($P\leq0.1$) between background/baseline data and the outcome of current pain intensity and NDI (*AROM* active range of motion)

Background/baseline data	Current pain outcome		NDI outcome	
	r-value	*P*-value	*r*-value	*P*-value
Gender	0.38	0.01	0.32	0.05
Age	–0.20	0.07		
Education			–0.17	0.02
Smoking	–0.10	0.02	–0.15	0.006
Segmental kyphosis	–0.20	0.07	–0.23	0.05
Neck AROM flexion			–0.33	0.005
Neck AROM right rotation	–0.20	0.08	–0.40	0.0009
Neck AROM right lat. flex.			–0.18	0.10
Right handgrip strength	–0.25	0.03	–0.32	0.009
Left handgrip strength	–0.20	0.09	–0.21	0.08
Current pain intensity	0.33	0.006	0.26	0.02
Pain drawing	0.40	0.03	0.41	0.01
NDI	0.33	0.007	0.51	<0.0001

Multivariate analysis

The standard linear multiple regression model showed that predictors for pain reduction were male gender, greater segmental kyphosis, non-smoking, greater neck AROM in right rotation, low disability on NDI, and older age. The adjusted R^2 was 0.30 ($P<0.0001$), which means that these preoperative variables explained 30% of the postoperative current pain intensity on VAS. Only gender ($P=0.03$), kyphosis ($P=0.005$) and age ($P=0.03$) were significant as single independent variables in the standard multiple regression model.

The best predictor from forward stepwise regression analysis of the postoperative current pain intensity on VAS was the magnitude of the preoperative kyphosis (adjusted $R^2=0.09$, $\beta=-0.32$) (Table 3).

Neck Disability Index

Bivariate analysis

Twelve preoperative variables: male gender, higher education, non-smoking, greater segmental kyphosis, greater neck AROM in flexion, right rotation and right lateral flexion, greater right and left handgrip strength, absence of non-organic pain drawing patterns, low current pain intensity on VAS, and low disability on NDI were significantly ($P\leq0.1$) correlated to a low postoperative disability on NDI at the last follow-up (Table 2).

Gender, neck AROM in right rotation and right lateral flexion, left handgrip strength, and pain drawing were excluded from the multiple regression models because they reduced the adjusted R^2 value. The initial NDI variable was also excluded from the multiple regression models, in order to reduce the number of independent variables.

Multivariate analysis

The standard linear multiple regression model showed that the best predictors for low disability on the NDI were higher educational level, non-smoking, greater segmental kyphosis, greater neck AROM in flexion, greater right handgrip strength, and low current pain intensity. These preoperative variables explained 28% of the postoperative NDI score (adjusted $R^2=0.28$, $P=0.002$). The only significant independent variable in the multiple model was right handgrip strength ($P=0.02$).

The best predictor of postoperative NDI from forward stepwise regression analysis was the initial current pain intensity (adjusted $R^2=0.13$, $\beta=0.28$) (Table 4).

Remaining problems

Before surgery most of the patients reported a deficit as measured by current pain intensity (87 patients = 99%) and NDI criteria (84 patients = 96%).

Table 3 Stepwise regression analysis for current pain intensity after surgery for cervical disc disease (*n*=74)

Measure	Cumulative adj. R^2 by step	β	*b*	Standard error *b*
Kyphosis	0.09	–0.32	–1.70	0.56
Gender	0.19	0.29	18.15	6.54
Age	0.24	–0.24	–0.94	0.40
Smoking	0.29	–0.24	–14.72	6.53

Table 4 Stepwise regression analysis for the NDI after surgery for cervical disc disease (*n*=75)

Measure	Cumulative adj. R^2 by step	β	*b*	Standard error *b*
Current pain	0.13	0.28	0.14	0.06
Smoking	0.18	–0.24	–5.15	2.32
Flexion	0.23	–0.24	–0.16	0.08

At the last follow-up the number of patients with a deficit was reduced. Seventy percent had a deficit on the current pain intensity criteria, 71% on NDI criteria, and according to Odom's criteria, 44% were rated as fair or poor. Sixty percent of the patients had deficits both on current pain and on NDI criteria at the last follow-up.

Postoperative radiographic variables

In a bivariate analysis, postoperative kyphosis, change of kyphosis, and postoperative segmental height were not correlated with either postoperative current pain intensity or NDI.

In the CP group there were six patients (14%) with pseudarthrosis in at least one level, compared to 18 patients (38%) in the CIFC group (P=0.01). There was no significant correlation between healing status (fusion/pseudarthrosis) and the outcome as measured by the NDI (r=0.27, P=0.5). But there was a significant correlation (r-value 0.39, P=0.04) at follow-up between healing status and current pain intensity. The mean VAS pain intensity in the 65 patients (73%) with healed fusion was 33 mm (SD 30 mm) compared with 49 mm (SD 30 mm) in patients with pseudarthrosis (P=0.04).

Discussion

In the present study, current pain intensity after surgery was best predicted, in a forward stepwise analysis, by the magnitude of the preoperative segmental kyphosis. This finding cannot easily be explained. It may be that kyphosis reflects a truly symptomatic segment. That may mean that patients with an objectively verifiable radiographic finding have a better prognosis for a successful surgical outcome. In a previous analysis of the same material we found a correlation between greater postoperative kyphosis and an improved cervical spine functional score [29]. The findings suggested that kyphosis may result in a disengagement of the facet joints, and may thereby provide better pain relief than lordosis, which may compress and induce symptoms from degenerative facet joints. However, in the long term, kyphosis could be disadvantageous because of increasing degenerative changes at adjacent segmental levels [29].

Pain and disability have previously been established as important outcome measures in both low-back pain and non-specific neck pain patients [8, 19, 26]. In a study by Kjellman et al. [19], it was shown that different outcome variables were influenced by different predictive factors. Disability was influenced by high pain intensity, low general health, low expectations of treatment, and lengthy symptom duration. Pain was influenced by a high level of disability, lengthy symptom duration, and having suffered similar problems previously [19]. The use of different out-come variables and the use of different statistical analyses may explain why previous studies have reported a variety of predictive factors in ACDF. In the present study the predictive factors for outcome of pain intensity and NDI were quite similar in the Spearman rank correlation coefficient analysis.

In view of the strong correlation between current pain intensity and NDI before and after surgery, it was not surprising that current pain intensity in a forward stepwise regression was the most important predictor of NDI after surgery.

Smoking has earlier been shown to be a risk factor not only for developing cervical and lumbar disc disease [1] but also for pseudarthrosis after ACDF [2]. In this study there was no correlation between smoking and pseudarthrosis. However, smoking was an important factor for both pain intensity and functional outcome. It is possible that smoking habits are associated with outcome by factors other than the strictly biological effects of tobacco.

Type of surgery did correlated with outcome, despite the fact that pseudarthrosis was much more common in patients operated on with the CIFC [29] compared to CP. Furthermore, there was a significant but limited correlation between pseudarthrosis and postoperative pain, but no correlation between pseudarthrosis and postoperative NDI. The reason for this discrepancy is difficult to explain; one should expect a worse outcome with the CIFC, since pseudarthrosis was much more common with the cage. It is possible that the large variation in outcome makes it difficult to document differences in outcome statistically, or else that outcome is in fact not affected by pseudarthrosis.

In this current study, the neck AROM and handgrip strength had a predictive value for outcome on pain and disability, even though it is weak. This is not surprising, since few previous studies have proven any relation to neck pain [13]. The use of handgrip strength can be looked upon either as a measure of general health or as a measure of injury or disease [5, 18, 20]. The latter suggestion would support handgrip strength being a specific measure for patients with cervical radiculopathy. The latest research of activation patterns suggests that, instead of peak performance, other parameters of muscle performance in other types of motion must be implanted [15].

As previously shown by Eriksen et al. [9], female gender was a predictor for a poor outcome after surgery. A significant correlation (r=0.58, P=0.0002) between gender and initial pain drawing may be a reason why pain drawings had no predictive value for postoperative pain intensity in the multiple regression model when gender was included in the model.

In the standard multiple regression analysis for outcome of NDI, education has some importance and may reflect a difference in work load [4, 10], which, in turn, may affect function (NDI). This proposition is supported by our finding of greater pain and disability in blue-collar than white-collar workers.

In this study, older age surprisingly predicted decreased pain intensity after surgery. This finding contradicts results from previous studies that have shown older age either to be a predictor of poor outcomes [3, 9], or to have no predictive value [14]. The reason for this discrepancy is unclear.

The relatively low adjusted R^2 suggests that other factors, such as psychological and stress-related factors, neck muscle strength and endurance, leisure time and general health, may be important predictors of outcome, not quantified in the present study.

At the last follow-up, about 70% of the patients still had remaining problems based on pain VAS≥10 mm and NDI≥20%. Similar results 1 year after surgery with CP and CIFC have been reported previously [16, 23]. These problems may reflect inadequate patient selection. The patients in this study do not differ in regard to age, duration of symptoms, or number of operated segmental levels, in comparison with other studies [3, 12]. The proportion of patients with remaining problems was lower (44%) when estimated by Odom's criteria. The findings are in accordance of previous results showing that outcome is influenced by the method by which it is measured [16]. This is a reflection of different perspectives, and shows that it is important to evaluate the effects of surgery with a set of broad and distinct outcome measures.

The large number of patients with remaining deficit after surgery suggests that surgery at one or two levels cannot be expected to solve a patient's total problem. However, we have no knowledge regarding the effect of different forms of complementary rehabilitation.

Conclusion

The results of the study clearly show the need for improved methods of patient selection in ACDF. The fact that greater segmental kyphosis is a good predictor of pain intensity outcome strongly suggests that the segment contains organic and truly symptomatic disease, and shows that an objective radiological variable may be useful in the selection of patients for ACDF. However, patients' own experience of pain was the most important factor for predicting the broader outcome of NDI.

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